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AcroMed Anterior Cervical Stabilization System
510(k) Summary

June 11, 1997

COMPANY: **AcroMed Corporation**
3303 Carnegie Avenue
Cleveland, Ohio 44115

TRADE NAME: **AcroMed Anterior Cervical Stabilization System**

CLASSIFICATION: Orthosis, fixation, spinal cervical intervertebral body. Class II

DESCRIPTION:

The AcroMed Anterior Cervical Stabilization System, in its fully assembled form, consists of two laterally placed rods joined by platforms which lie on the anterior vertebral surface. The system is anchored to the vertebrae with screws. The implant provides supplemental stability to the cervical spine following anterior cervical fusion. Depending upon the implant configuration, it may serve as either a fixed (load-bearing) or unfixed (load-sharing) construct.

The following types of components are available in the system: Rods, Platforms, Screws and Cross Connectors. All components are manufactured from implant grade Titanium alloy which conforms to ASTM F136 specifications. Assemblies are also available for convenience of the surgeon. These are pre-assembled partial constructs consisting of one Platform, one Cross Connector, two Rods and two Locking Screws.

An instrument set is available specifically designed for use with the AcroMed Anterior Cervical Stabilization System.

Rod:

Precontoured Rods comprise the longitudinal structures of the system. All Rods have a 3mm outer diameter and an integral head. Eight lengths are available: 21mm, 36mm, 43mm, 51mm, 58mm, 65mm, 85mm and 110mm. Two rods are required for each construct. Rods may be cut to the appropriate length during the procedure if required. The Rods are precontoured to a curvature consistent with the cervical lordosity, but additional contouring using the Construct Bender contained in the instrument set may be performed if required.

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Platform:

Five Platform designs are available which are designed to connect the Rods and anchor to the vertebral bodies with bone screws. All Platforms may be used with either Solid Bone Screws (for bicortical fixation) or the combination of Outer and Inner Bone Screws (a hollow outer bone screw used with a solid inner locking screw designed for unicortical fixation). Screw selection is determined by physician preference. All Platforms are designed to be used with two Rods in forming the construct.

Platforms are available in Lockable and Non-Locking designs. Lockable Platforms are recommended for use at the caudal end of all constructs. If a fixed configuration is preferred to a non-fixed (i.e., load-sharing) configuration, a Lockable Platform must also be utilized at the rostral end of the construct. If a load-sharing configuration is desired, the rostral-most Platform is not locked to the Rods.

Three Platforms are designed for angled insertion of the screw into the vertebral body. The resulting screw angle is thirty degrees and may be directed either rostrally or caudally. These Platforms have a fin feature on one side which engages the vertebra from within the disk space for optimal positioning and fixation. Two of these three Platforms are lockable and thus may be utilized at either the rostral or caudal end of the construct. Lockable Platforms (Type C and Type H) have extensions which accept Platform / Cross Connector Locking Screws for securing the Platform to the Rods. Selection of Type C versus Type H Platforms is based on physician preference and patient anatomy. The third Platform for Angled Screws does not lock to the Rods, and thus is not designed for use at the caudal end of the construct.

Two Platforms are designed for straight (perpendicular) insertion of the screw into the vertebral body. They are available in both lockable and non-locking designs. As described above, the Lockable Platform for Straight Screws may be utilized at either the rostral or caudal end of the construct. The Non-Locking Platform for Straight Screws does not lock to the Rods, and thus is not designed for use at the caudal end of the construct.

One Platform design is available for fixation of the construct to an intervertebral graft. This Platform features a horizontal slot and spherical nest to accommodate variation in screw entry site and in trajectory into the graft.

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Assembly:

As mentioned in the overall device description, Assemblies are pre-assembled, partial constructs consisting of one Platform, one Cross Connector, two Rods and two Platform / Cross Connector Locking Screws. They are provided for the convenience of the surgeon. Assemblies are provided in five lengths ranging from 36mm to 65mm. All five available Assemblies utilize a Platform for Angled Screws, Lockable, Type H.

Cross Connector:

Cross Connectors are used to connect and lock to the two Rods. They have a "band clamp" design in which the upper and lower halves of the Cross Connector are squeezed together by the Platform / Cross Connector Locking Screws, clamping the Cross Connector to the Rod. The Cross Connector does not provide for fixation to the vertebra. It is intended to provide torsional stability in longer constructs.

Outer Bone Screw:

Outer Bone Screws are designed to be used in conjunction with Inner Bone Screws. They are available in three diameters: 3.75mm, 4.0mm and 4.35mm. Each diameter is available in four lengths: 10mm, 12mm, 14mm and 16mm. The Outer Bone Screw has an expanding screw head which locks to the Platform. It also has a screw tip which, like the screw head, expands upon full insertion of the Inner Bone Screw. The combination of Outer and Inner Bone Screws is intended for unicortical fixation.

Inner Bone Screw:

Inner Bone Screws are available in four lengths: 10mm, 12mm, 14mm and 16mm. Insertion of the Inner Bone Screw into the Outer Bone Screw results in expansion of the Outer Bone Screw head (thus, locking the screw to the Platform) as well as expansion of the Outer Bone Screw tip.

Solid Bone Screw:

Solid Bone Screws are available in two diameters: 3.75mm and 4.0mm. Each diameter is available in eight lengths ranging from 16mm to 24mm. The Solid Bone Screw is designed for bicortical fixation.

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Platform / Cross Connector Locking Screw:

The Platform / Cross Connector Locking Screw is designed for two purposes. First, it is used to tighten together the two sides of the Cross Connector ("band clamp" design), thus locking it to the Rods. Second, it is used to lock a Platform to the Rods. It is available in only one size.

Graft Screw:

The Graft Screw is a solid screw design which is specifically designed to be used with the Platform for Graft Fixation. It is available in only one size, with a diameter of 3.5mm and a length of 10mm. The head of the Graft Screw is designed to match the Platform for Graft Fixation.

PERFORMANCE DATA:**Non-Clinical:**

Static bending compression and torsion were performed on the system to characterize its mechanical properties. Additionally, testing was also performed to characterize fatigue life. Finally, quasi-static range-of-motion studies were performed in axial compression/tension and torsion to characterize the system's displacement during loading.

INTENDED USE:

The AcroMed Anterior Cervical Stabilization System is intended for anterior cervical intervertebral body fixation. This system is indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indications include symptomatic cervical spondylosis, trauma (including fracture), post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), re-operation for failed fusion, or instability following surgery for the above indications.

SUBSTANTIAL EQUIVALENCY

TOP Cervical Spine Stabilization System



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1997

Ms. Sally L. Levine
Product Approval Partner
Clinical and Regulatory Affairs
AcroMed Corporation
3303 Carnegie Avenue
Cleveland, Ohio 44115

Re: K970955
AcroMed Anterior Cervical
Stabilization System
Regulatory Class: II
Product Code: KWQ
Dated: March 14, 1997
Received: March 17, 1997

Dear Ms. Levine:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market your device system subject to the general controls provisions of the Act and the limitations identified below.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment would cause the device system to be adulterated under 501(f)(1) of the Act.

FDA identifies that any device system, if intended for use in pedicular screw fixation/attachment, except for some limited indications, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. You may not label or in any way promote this device system for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. Therefore, in order to prevent off-label promotion, the package insert must include the following statement, "**WARNING:** This device system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.";
2. All labeling for this device system, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system is intended for the specific use(s) described in the enclosure only; and
3. Pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column, except for limited indications, of any device system is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device system for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic

GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

FDA advises that the use of the subject device system and/or device components with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or other manufacturers', may also be required.

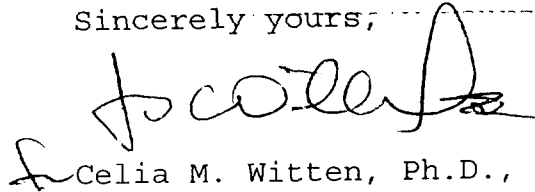
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

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obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "C. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K970955

Device Name: AcroMed Anterior Cervical Stabilization System

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

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Prescription Use X

(per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)